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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,235	08/17/2006	Heng-Mao Chiu	SPR04388P00150US	2268
32116	7590	12/06/2010	EXAMINER	
WOOD, PHILLIPS, KATZ, CLARK & MORTIMER			HUPCZEY, JR, RONALD JAMES	
500 W. MADISON STREET				
SUITE 3800			ART UNIT	PAPER NUMBER
CHICAGO, IL 60661			3739	
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			12/06/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,235	CHIU ET AL.	
	Examiner	Art Unit	
	RONALD HUPCZEY, JR	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09/23/2010.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6,8,10-17 and 20-24 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-6,8,10-17 and 20-24 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 23 September 2010 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09/23/2010</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. Applicant's response, dated September 23rd, 2010 is fully acknowledged by the Examiner. Currently claims 1-6, 8, 10-17 and 20-24 are pending with claims 1-6, 8, 10-17 and 22-23 amended and claims 7, 9, 18-19 and 25-45 cancelled. Applicant's amendments to the claims have obviated the previously filed objections to the claims as well as the rejections of the claims under 35 U.S.C. 112, 2nd paragraph. Applicant's amendments to the specification are accepted and have obviated the object to specification regarding the use of trademarks. The following is a complete response to the September 23rd, 2010 communication.

Drawings

2. Applicant's submission of new figure 1(d) is accepted by the Examiner. Upon inspection of the newly submitted drawing and the subject matter represented therein, it is the Examiner's position that each of the features displayed in the drawing are adequately supported in the specification (see page 9, lines 25-26 of the 09/23/2005 specification discussing the placement of the Teflon sheath and page 6, lines 8-9 discussing the placement of the temperature sensor). It is also noted that the previously filed objections to the drawing have been obviated

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-6, 8, 10-17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ito et al (US Pat. No. 5,026,959) and further in view of Chin et al (US Pat. No. 6,802,840).

Regarding claim 1, Ito discloses a microwave antenna for medical ablation (see at least figure 1) comprising a transmission line (cable **10**) having an inner conductor (inner conductor **1**), an outer conductor (outer conductor **3**) and a dielectric insulator (dielectric **2**) to provide insulation between the inner and outer conductors of the transmission line. Ito further discloses an energy-emitting antenna element (second cable **11**) positioned at the distal end of the transmission line to transmit a microwave near-field (see figure 1) wherein the antenna element has an inner conductor (inner conductor **1** of cable **11**) electrically coupled to the inner conductor

of the transmission line (see figure 1) and a sheath of dielectric insulator around the inner conductor (dielectric **2** of cable **11**) of the antenna element and wherein the antenna element comprises a metallic conducting cap (cap **5** as disclosed in claim 9 of Ito as a conductor) electrically connected to the distal end of the inner conductor (see figure 1) such that the cap surrounds a length of the sheath of insulator (as seen in figure 1) and the dimensions of the cap are determined to provide impedance matching between the antenna element and the transmission line (see col. 3; 3-14 and claim 7). Ito also discloses that the antenna element is configured with conducting rings (ring conductors **4**) spaced apart from each other along its length by slots (slits **7**). Ito fails to disclose that the antenna element is configured by being bent to form an open loop oriented such that it extends transverse to the longitudinal axis of the transmission line. Chin discloses a microwave treatment device in which the antenna element is bent to form an open loop transverse to the longitudinal axis of the transmission line (see figure 12) in order for the device to better conform to the desired target treatment surface (see col. 8; 31-39). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to shape the device of Ito in the open loop shape of Chin in order to better form desired lesion patterns. Such an open loop shape prevents the inadvertent and undesired treatment of non-target tissue and allows for circular lesions to be formed around, for example, the pulmonary vein of the heart.

Regarding claim 2, Ito discloses that at least one of the particular dimensions of the metallic cap listed in claim 2 are determined in order to form the cap **5**. It is noted by the Examiner that the limitation of “determined” is rather broad when taken in combination with the various length and radius dimensions. In the broadest reasonable interpretation and as is being

applied by the Examiner, if the dimension of the prior art device exists, it is therefore being taken as being determined. In the instance case, it is clear that the cap **5** as in figure 1 has a length as well as a radius and surrounds a length of the sheath of insulator. The same standard will be applied for the remaining claims.

Regarding claim 3, Ito discloses that the antenna element is coupled to the end of the transmission line, and the cap is coupled to the inner conductor of the transmission line (see figure 1, cables **10** and **11** joined; placement of cap **5** in relation to inner conductor **1**).

Regarding claim 4, Ito discloses that a first length of the outer conductor of the transmission line is removed from the distal end of the transmission line to create the antenna element (see at least figure 1).

Regarding claim 5, Ito discloses that a short length of the dielectric insulator is removed from the distal end to expose a length of the inner conductor of the transmission line for fixing of the cap (see figure 1, inner conductor **1** within cap **5**).

Regarding claim 6, Ito discloses that the length of exposed inner conductor of the transmission line between the distal end of the sheath of insulator and the cap is determined (see figure 1).

Regarding claim 8, Ito discloses that the antenna element comprises insulating rings in the slots and conducting rings placed alternately along the length of insulating sheath (ring conductors **4** separated by slits **7**).

Regarding claim 10, Ito discloses that the conducting rings comprise rings of the outer conductor (ring conductors **4** with same diameter as outer conductor **3**).

Regarding claim 11, Ito discloses that the cap is made using a conducting ring (cap **5** disclosed as conducting as in claim 9).

Regarding claim 12, Ito discloses that the sizes of the conducting rings and the slots between the conducting rings are selected to determine the shape of the near-field distribution (see col. 4; 59-68).

Regarding claim 13, Ito discloses that the conducting rings are the same size, and all the slots between the conducting rings are the same size (see spacing in figure 1 and see claim 2).

Regarding claim 14, Ito fails to specifically recite that the conductive rings are twice as wide as the slots between the conducting rings. However, Ito does disclose that the slots (slits **71**) and the rings (ring conductors **4**) are adjustable in size and that such an adjustment allows for the antenna to match the desired microwave treatment frequency (see col. 4; 32-34). Ito also discloses that any of the plurality of measurements of the rings and slots can be adjusted (see col. 4; 54-64). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the rings twice as wide as the slots between them to obtain a desired treatment depth with respect to the desired treatment frequency. While Applicant has set the desired measurement relation on at least pages 5 and 11 of the specification, much of the disclosure is directed towards adjusting the respective measurements to find optimal widths. No criticality or unexpected results have been set forth by Applicant with respect to the claimed measurements. Additionally, it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claim 15, Ito fails to disclose that the slot and ring sizes gradually increase towards the tip of the antenna makes a forward firing antenna. Ito does disclose, with respect to claim 16 above, that the sizes gradually decrease towards the tip. Additionally, Ito discloses that the slots (slits **71**) and the rings (ring conductors **4**) are adjustable in size and that such an adjustment allows for the antenna to match the desired microwave treatment frequency (see col. 4; 32-34). Ito also discloses that any of the plurality of measurements of the rings and slots can be adjusted (see col. 4; 54-64). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to increase the size of the slots and rings gradually in order to obtain a desired treatment depth with respect to the desired treatment frequency. While Applicant has set the desired measurement relation on at least page 14 of the specification, much of the disclosure is directed towards adjusting the respective measurements to find optimal widths. No criticality or unexpected results have been set forth by Applicant with respect to the claimed measurements. Additionally, it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claim 16, Ito discloses that the slot and ring sizes gradually decrease towards the tip of the antenna thereby making a reverse-firing antenna (see claim 5).

Regarding claim 17, Ito discloses that the dielectric loading produced by the length of the insulator surrounded by the cap is determined to ensure the near field flow terminates at the tip of the antenna rather than at the transmission line/antenna element junction (see col. 5; 1-8).

Regarding claim 19, as with claim 11 above, the open loop form of the antenna element is being taught by Chin. In order to form the open loop, at least one of the dimensions of: the straight length of the sheath of insulator before bending begins, the radius of bending between the transmission line and the open loop, the perpendicular distance between the open loop and the beginning of bending, the radius of the open loop, the length the cap not surrounding the sheath of insulator and the perpendicular distance between the top of the cap and the transmission line would need to be determined. As such, it is the Examiner position that in view of the combination of Ito in view of Chin, that at least one of the above dimensions would be an obvious consideration. It is again noted by the Examiner that the limitation of “determined” is rather broad when taken in combination with the various length and radius dimensions. In the broadest reasonable interpretation and as is being applied by the Examiner, if the dimension of the prior art device exists, it is therefore being taken as being determined.

7. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ito et al (US Pat. No. 5,026,959) in view of Chin et al (US Pat. No. 6,802,840) and further in view of Edwards et al (US Pat. No. 6,033,401).

Regarding claim 20, Ito discloses that the antenna comprises a sheath surrounding at least the antenna element (protective layer **9**) but fails to disclose the material of construction to be Teflon. Edwards discloses a microwave treatment device (see figure 1) in which the elongate body **12** is coated with a Teflon coating (see col. 5; 1-5). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the protective layer **9** of Ito out of Teflon to provide for a device which has a reduced chance of sticking to the

surrounding treated tissue. It is further noted that the use of Teflon to coat devices, as demonstrated by Edwards, is well known and commonly utilized in the art.

8. Claims 21 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ito et al (US Pat. No. 5,026,959) in view of Chin et al (US Pat. No. 6,802,840) and further in view of Elliott (US Pat. No. 4,800,899).

Regarding claim 21, Ito fails to disclose that the antenna element is delivered to an ablation site by feeding the transmission line through a catheter. Elliott discloses a similar microwave antenna as that of Ito and discloses in figure 5 that the antenna is delivered through a catheter (catheter **73**). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to size the antenna of Ito to a diameter suitable for insertion through a catheter. It is noted that the use of a catheter to insert a treatment device is old and well known in the art and one of ordinary skill would readily appreciate the insertion of a microwave antenna in this manner.

Regarding claim 24, Ito fails to disclose a computer control system to monitor or the ablation process and control the microwave generator. Elliott discloses a similar microwave antenna as that of Ito and further discloses the present of a computer control system (see figure 1, apparatus **10**) which controls the microwave generator (generator **14**) and monitors the ablation process (by use of sensors **42**). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the computer control system of Elliott with the antenna of Ito to provide a well known manner of controlling the application of microwave energy to the target treatment site.

9. Claims 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ito et al (US Pat. No. 5,026,959) in view of Chin et al (US Pat. No. 6,802,840) and further in view of Kasevich (US Pat. No. 5,057,106).

Regarding claim 22, Ito fails to disclose that the antenna comprises a temperature sensor to sense the temperature of the tissue. Kasevich discloses a microwave treatment system comprising an antenna (array **12**) containing at least one temperature sensor (sensors **29, 31, 33 and 35**) for sensing temperature. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a temperature sensor of Kasevich in combination with the antenna of Ito to provide for a combined device which can relate tissue temperature to a user. The provision of such ensures that the target tissue is heated in excess thereby reducing the chance of burning or charring of tissue and effectively limiting overall lesion size.

Regarding claim 24, Ito fails to disclose a computer control system to monitor or the ablation process and control the microwave generator. Kasevich discloses a similar microwave antenna as that of Ito and further discloses the present of a computer control system (Systems **s1** and **s2**) which controls the microwave generator and monitors the ablation process (by use of sensors **29, 31, 33 and 35**). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the computer control system of Kasevich with the antenna of Ito to provide a well known manner of controlling the application of microwave energy to the target treatment site.

10. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ito et al (US Pat. No. 5,026,959) in view of Chin et al (US Pat. No. 6,802,840) and in view of Kasevich (US Pat.

No. 5,057,106) as applied to claim 22 above, and further in view of Elliott (US Pat. No. 4,800,899).

Regarding claim 23, Ito and Kasevich fail to specifically recite a microwave generator delivering energy at 2.45 GHz. Elliott discloses that the application of microwaves at 2450 MHz (2.45GHz) is common by generators known in the art (see col. 4; 37-46) and that such is advantageous because it is an FCC approved frequency (see col. 6; 50-62). Therefore, it would have been obvious to utilize a well known microwave generator such as that disclosed in Elliott in combination with the antenna of Ito to provide for a device which provides an exemplary and commonly utilized frequency of microwave energy to a target treatment site.

Response to Arguments

11. Applicant's arguments filed September 23rd, 2010 have been fully considered but they are not persuasive. Applicant has provided an outline on pages 11-12 of the Remarks of the claimed subject matter of amended claim 1 and has alleged on page 12 that Ito fails to "specify the size, materials, the microwave frequency or the use of the device in any detail" to the extent that Ito "does not anticipate or even suggest the claimed invention as amended". Other than this allegation, no specific reasoning can be found as to why each of the references cited in the prior office action does not adequately anticipate or fairly suggest each of the limitations of the instant claims. In response to these allegations, it is noted by the Examiner that Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. Also, Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or

she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Furthermore, they do not show how the amendments avoid such references or objections. As a result, it is the Examiner belief that the above rejections clearly outline the Examiner's position as to why each reference and combination of references remains tenable over the pending claims and that the above rejections are fully response to Applicant's remarks.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD HUPCZEY, JR whose telephone number is (571)270-5534. The examiner can normally be reached on Monday - Friday, 9 A.M. to 5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ronald J. Hupczey/
Examiner, Art Unit 3739

RJH

/Michael Peffley/
Primary Examiner, Art Unit 3739